



March 31, 2005

Mr. Gary M. Jackson  
Assistant Administrator for Size Standards  
Office of Size Standards  
U.S. Small Business Administration  
409 Third Street, S.W.  
Washington, D.C. 20416

Dear Administrator Jackson:

The Biotechnology Industry Organization (BIO) is pleased to respond to the U.S. Small Business Administration's (SBA's) request for comments on the December 3, 2004 Advance Notice of Proposed Rulemaking (ANPRM) on whether an exclusion from affiliation for venture capital companies (VCCs) should be provided in size determinations for eligibility in the Small Business Innovation Research (SBIR) program (69 Fed. Reg. 70197).

BIO is a trade association representing over 1000 biotechnology companies, academic institutions, State biotechnology centers, and related organizations in all 50 states. BIO members are involved in the research and development of healthcare, agricultural, industrial, and environmental biotechnology products. Our membership represents a complete cross-section of the industry, from small, research-based start-ups to mid-sized and large, well-established biotechnology companies. The vast majority of BIO members are emerging companies focusing on the research and development of new products, goods or services flowing from biotechnology.

The ANPRM seeks comments on two issues: (1) SBA's approach to restructuring size standards; and (2) whether SBA should disregard its affiliation rules for SBIR program purposes and allow business concerns that are majority owned or controlled by a VCC to be eligible for SBIR awards, regardless of any affiliations arising from the ownership and control of the VCC. BIO urges SBA to address the VCC issue expeditiously and separately from SBA's initiative to re-evaluate size standards, given that the two issues are distinct.

BIO notes that SBA recently issued a Final Rule (69 Fed. Reg. 70180) on a related subject. That Final Rule amended SBIR eligibility requirements to include a concern that is at least 51% owned and controlled by another for-profit business concern so long as that firm is itself

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at least 51% owned and controlled by one or more individuals who are citizens of, or permanent resident aliens in, the United States. This change would ostensibly permit venture capital ownership of a SBIR awardee, but only if the VCC owned and controlled 51% of the SBIR awardee and the VCC itself was 51% owned and controlled by individuals.

BIO supports SBA's recent rulemaking and commends SBA for its ANPRM seeking public input. However, neither the Final Rule nor the ANPRM's proposed approach address the fundamental obstacle to participation of small biotechnology companies in the SBIR program – i.e. SBA's requirement that small business firms be majority owned and controlled, directly or indirectly, by "individuals," which is interpreted not to include business entities. For reasons previously advanced, BIO believes the scope of the ANPRM should be broadened to include corporations and other business entities in the definition of "individuals" in 13 C.F.R. § 121.702.

### **Venture Capital Funding is Crucial For Small Biotechnology Companies**

Before most biotechnology products can become commercially available, years of work and hundreds of millions of dollars of capital are required to complete testing and gain product approvals. While there are many different funding strategies, the typical form of investment in promising, early-stage companies is venture capital. Such capital comes primarily from VCCs, whose interests are usually owned by a combination of individual investors, business entities and pension funds. After the initial seed funding is invested in support of basic R&D, a typical biotechnology company seeks venture capital investments to allow it to expand R&D and eventually launch commercial operations. Because of the significant funding required to bring biotechnology products to market, very few biotechnology companies are capable of commercializing their technologies without significant VCC backing. Illustrating this point is the fact that in 2003 venture capital investments in the biotechnology and medical device industry totaled \$5.1 billion. <sup>1/</sup>

Biotechnology companies seek venture capital investment from a variety of sources. Each source is generally interested in one type of project, while the biotechnology company is capable of performing research in a number of different areas. Nonetheless, the receipt of venture capital support, in turn, results in a diversified ownership structure. Because of the large amounts of funding required, and the high risks involved in backing a start-up company, a single venture capital investor may not invest sufficient amounts to give it a majority ownership position in a small biotechnology company. Rather, in most cases a *combination* or "syndicate" of venture firms will together own more than 51% of the company. When no *single* VCC owns or controls the firm, SBA's affiliation rules generally do not come into play, and thus the VCC investment does not by itself disqualify the small company. Thus, disregarding affiliation with such VCCs may have limited or no impact on eligibility. However, because SBA has interpreted "individual" to exclude corporate and other business entities, a small business that is majority owned by *multiple* VCCs will not qualify, even under the limited exception included in the Final Rule issued on December 3, 2004.

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<sup>1/</sup> See Money Tree Survey –Price Waterhouse Coopers, available at <http://www.pwcmoneytree.com>.

## **Many Small Biotechnology Companies Are Excluded From the SBIR Program**

In early 2005, BIO conducted an informal survey of members that are active in the SBIR community, or were prior and/or potential SBIR grantees. The results of the survey confirm that SBA's current SBIR size standard is severely limiting and discouraging small biotechnology companies from participating in the SBIR program. For instance, over 70% of the survey respondents were small businesses with less than 50 employees, and over 80% were privately owned. Of the privately owned companies, 70% are majority owned and controlled by *multiple* VCCs. The number of VCCs that have an equity stake in the small businesses range from 2 to 22. Only one VCC has an equity stake greater than 40% in the survey respondents, while most VCCs owned between 7% and 30% of the small businesses.

Over the last 5 years, 62% of the survey respondents (public and private companies) applied for SBIR grants. Exactly half of these applicants were either denied SBIR grants immediately because they could not meet the SBIR size standard due to their ownership structure, or were subsequently denied the grant due to an adverse size determination. Interestingly, over 60% of the privately owned companies chose not to even apply for SBIR grants due to perceived eligibility concerns.

The survey results are illustrated by the following examples of companies that have been excluded from the SBIR program due to their diversified ownership structure. For instance, a company in Florida originally received venture capital funding to support a breakthrough technology in gene therapy for treating an important genetic disease called alpha-1-anti-trypsin deficiency. In addition, this technology was being investigated to treat other rare metabolic diseases. The company successfully competed for a SBIR grant to develop a product candidate for the rare genetic disorder affecting children called Pompe's disease. However, funding for this grant was ultimately denied because SBA determined that the company was majority owned and controlled by multiple VCCs. Thus, a new promising therapy for children is not being developed and no new employees were hired for this project. In addition, potential cures for all the other diseases that were to be investigated as a result of the SBIR grant (e.g., chronic neurological diseases, cardiac diseases, and others) could not be pursued. Ironically, had the company's ownership structure included one very large VCC which was 51% owned by individuals (i.e., about 26% indirect individual ownership) -- instead of its actual more diverse ownership by several smaller VCCs -- it would have qualified for the grant.

Similarly, a small biotechnology company received several SBIR grants for developing new products to treat autoimmune diseases, cancer, and infectious diseases including many of the Class A and B biothreat agents. However, due to SBA's recent interpretation of SBIR eligibility requirements, the company has been foreclosed from building upon its prior research and applying for new SBIR grants to develop a candidate therapy to treat lymphoma and leukemia, in addition to a vaccine discovery effort to identify new candidates to prevent plague. The small business had also hoped to get additional SBIR funding to support clinical candidates to treat autoimmune diseases, a new vaccine to prevent West Nile virus, a therapy to prevent West Nile disease, and support for a very promising technology to treat many types

of cancers. Unfortunately, all of these projects have been put on hold due to the rigid SBIR size standard.

The legislative history of the SBIR program makes it abundantly clear that Congress intended for the SBIR program to assist small businesses to commercialize their creations and products. Congress' intent, when implementing the SBIR program, was to *stimulate small U.S.-owned firms to produce innovative technologies*. When Congress enacted the SBIR program, it very clearly recognized and endeavored to encourage the symbiotic relationship between VCCs and the small technology firms. For example, there is an entire section of the relevant Committee Report detailing the importance of encouraging private investment. Indeed, the Committee concluded that:

providing small firms with R&D seed money ... will encourage additional private investment in these firms. The agency-wide SBIR program outlined in the legislation should facilitate the ability of participating firms to attract venture capital as well as other financial commitments from the private sector.<sup>2/</sup>

Congress viewed the SBIR program as providing the necessary “proof of concept” to encourage venture capital investment in promising small businesses seeking to bring products from the workshop to the marketplace. Moreover, Congress even created a Phase II SBIR preference for companies that attracted venture capital investment by providing:

*special consideration in the funding review of Phase II proposals to applicants who are successful in attracting private capital commitments to pursue commercial applications of the Federal research.* This special consideration is given by awarding extra points of merit to those proposals that have attracted private sector commitments for follow-on funding.<sup>3/</sup>

Thus, SBA's virtual exclusion of most venture-backed firms from the SBIR program is clearly at odds with stated Congressional purposes.

### **Recommended Changes to SBA Regulations**

BIO supports the ANPRM's approach for disregarding affiliation under the SBIR program. However, as explained above, the exclusion from the affiliation rules will have limited practical effect for many small biotechnology firms, because the fundamental flaw in the regulation requiring direct or indirect 51% ownership and control by natural persons remains.

The ANPRM specifically seeks alternative approaches that may assist small business concerns in obtaining and utilizing VCC funding while participating in the SBIR Program. BIO recommends that SBA adopt a rule that addresses the actual ownership structure of most small biotechnology companies. Specifically, BIO suggests that the size requirements, 13 C.F.R. §

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<sup>2/</sup> See S. Rep. No. 97-194, 97<sup>th</sup> Cong., 1<sup>st</sup> Sess. 1981, *reprinted in*, 1982 U.S.C.A.A.N. 512.  
<sup>3/</sup> Committee Report at 7-8 (emphasis added).

121.702, be clarified to permit both natural and artificial persons, including VCCs (irrespective of the VCCs' ownership), to count toward the 51% U.S. ownership and control requirement. Revising the definition of eligible persons will ensure that small biotechnology companies that are successful in attracting outside VCC investment will remain eligible for SBIR awards. Further, this clarification would reflect Congress' original intent when it established the SBIR program in 1982, and allow federal agencies to continue to support the cutting-edge research being conducted by small biotechnology companies.

BIO shares the Agency's concern that only genuine small businesses with promising technologies which are not dominated or controlled by other larger business entities receive SBIR awards. Maintaining existing affiliation rules will ensure that SBIR awards go to small businesses that are not majority owned or controlled by large VCC or other corporate entities.

In summary, we submit that continued reliance on a rule essentially requiring 51% individual ownership is counterproductive and will actually exclude many deserving small biotechnology businesses from the SBIR program. The simple answer to the current problem is to define the term "individuals" in the present regulation to include both natural and artificial persons. We also request that this change be made retroactive, to allow SBIR awardees whose grants have been revoked under the current interpretation of the regulations, the opportunity to continue to receive funding from this important source.

Please contact Morrie Ruffin at 202-962-6630 or Libby Solon at 202-962-9505 if you have any questions about these comments.

Sincerely,



James C. Greenwood  
President & CEO